

**MISSISSIPPI STATE DEPARTMENT OF HEALTH
DIVISION OF HEALTH PLANNING AND RESOURCE DEVELOPMENT
NOVEMBER 10, 2016**

**CON REVIEW NUMBER: ESRD-ES-0916-021
BIO-MEDICAL APPLICATIONS, INC.
D/B/A FRESENIUS MEDICAL CARE
DIALYSIS SERVICES OF RANKIN COUNTY - BRANDON
EXPANSION OF ESRD STATIONS
CAPITAL EXPENDITURE: \$19,700
LOCATION: BRANDON, RANKIN COUNTY, MISSISSIPPI**

STAFF ANALYSIS

I. PROJECT SUMMARY

A. APPLICANT INFORMATION

Bio-Medical Applications of Mississippi, Inc. d/b/a Fresenius Medical Care Dialysis Services of Rankin County – Brandon (“FMC-Brandon”) is a business corporation incorporated in Delaware and authorized to do business in Mississippi. The facility is located at 141 Gateway Drive, Brandon, Mississippi. Bio-Medical Applications of Mississippi, Inc. consists of two (2) directors and thirteen (13) officers. Bio-Medical Applications of Mississippi, Inc. is listed in good standing with the Office of the Secretary of State based on the Certificate of Good Standing dated May 28, 2015.

B. Project Description

Bio-Medical Applications of Mississippi, Inc. d/b/a Fresenius Medical Care Dialysis Services of Rankin County – Brandon requests Certificate of Need (CON) authority to expand its existing End Stage Renal Disease (ESRD) facility by six (6) ESRD stations. The facility is currently located at 141 Gateway Drive, Brandon, Mississippi and operates twenty-three (23) hemo-dialysis ESRD stations. However, the applicant indicates that on September 24, 2015, Bio-Medical Applications of Mississippi, Inc. d/b/a Fresenius Medical Care Dialysis Services of Rankin County – Brandon was granted Certificate of Need approval (CON # R-0898) by the Mississippi State Department of Health (MSDH) for The Relocation of an ESRD Facility Within One Mile and Expansion of ESRD Stations. Per CON # R-0898, FMC-Brandon proposed to relocate its entire facility within one mile of its current location at 141 Gateway Drive to 109 Mar Lyn Drive in Brandon, Mississippi. In addition, the applicant proposed to add seven (7) ESRD stations at its new location for a total of 30 ESRD stations.

The applicant now requests CON approval for an additional six (6) ESRD hemo-dialysis stations, which would result in a total of a thirty-six (36) station ESRD facility. The applicant states that the construction of the ESRD facility to be located at 109 Mar Lyn Drive in Brandon has commenced and is expected to be completed by Fall 2016. The applicant asserts that due to the increasing utilization rate at the existing

facility over the past year, the addition of six (6) ESRD stations is needed to meet the patient demand and ensure continuity/quality of care for its patients. The applicant suggests that approval of the proposed expansion, at this time will result in less patient and staff interruption.

The applicant received site approval from the Mississippi State Department of Health, Division of Licensure and Certification (Licensure) on September 9, 2016. The applicant states that the proposed project will not require any additional full time equivalents (FTE) personnel; however the applicant states that an annual cost of \$232,640 will occur for personnel.

The total capital expenditure for the proposed project is \$19,700 that applicant intends to finance with cash reserves. The applicant indicates the capital expenditure will be obligated within six-months after final CON approval and the proposed project will be complete within six-months of final CON approval.

II. TYPE OF REVIEW REQUIRED

This project is reviewed in accordance with Section 41-7-173 (b) of the Mississippi Code of 1972, Annotated, as amended, and duly adopted rules, procedures, plans, criteria, and standards of the Mississippi State Department of Health.

In accordance with Section 41-7-197(2) of the Mississippi Code 1972, Annotated, as amended, any affected person may request a public hearing on this project within 10 days of publication of the staff analysis. The opportunity to request a hearing expires on Monday, November 21, 2016 since the expiration date falls on Sunday, November 20, 2016.

III. CONFORMANCE WITH THE STATE HEALTH PLAN AND OTHER ADOPTED CRITERIA AND STANDARDS

A. State Health Plan (SHP)

The *FY 2015 State Health Plan* contains policy statements, criteria and standards, and service specific criteria and standards, which the applicant is required to meet before receiving CON authority for the expansion of an existing ESRD facility. This application requests a 6-station expansion of its existing ESRD facility. This application is in substantial compliance with applicable criteria and standards.

The *FY 2015 MSHP* state under the headings below:

Policy Statement Regarding Certificate of Need Applications for the Establishment of End Stage Renal Disease ESRD Facilities

PS (12) - Expansion of Existing ESRD Facilities: Existing ESRD facilities may add hemo-dialysis stations without Certificate of Need review, as long as the facility does

not add, over a period of two (2) years, more than the greater of four (4) stations or 15% of the facility's current number of certified stations.

As previously mentioned in this application, FMC-Brandon per CON # R-0898 was approved for the addition of seven (7) ESRD hemo-dialysis stations, according to PS (12) as contained in the *FY 2015 MSHP*. The notated CON # R-0898 was approved by the MSDH on September 24, 2015. Furthermore, the applicant is currently requesting to add six (6) additional ESRD hemo-dialysis stations.

Establishment of an End Sate Renal Disease (ESRD) Facility

SHP Criterion 1 – Establishment of New ESRD Facilities

The proposed application is not for the establishment of a new ESRD facility. Therefore, Criterion 1 is not applicable to the proposed project.

SHP Criterion 2 – Expansion of Existing ESRD Facilities

In the event that an existing ESRD facility proposes to add more than the greater of four (4) stations or 15% of the facility's current number of certified stations within a two-year period, then the facility must apply for a Certificate of Need and shall document that it has maintained a minimum annual utilization rate of 65% for the 12 months prior to the month of the submission of the CON application.

NOTE: ESRD Policy Statements 2, 4, 5 and 6, and Need Criterion 1, do not apply to applications for the expansion of existing ESRD facilities.

The applicant submitted the proposed project to request authority for the expansion of an existing ESRD facility. Since the proposed application will add six (6) ESRD hemo-dialysis stations and is within the two (2) year period of September 24, 2015, the facility is required to comply with this **SHP Criterion 2** as contained in the *FY 2015 MSHP*.

The *FY 2015 MSHP* shows that there are two ESRD facilities located in Rankin County: FMC-Brandon & NRI Brandon.

Per the *FY 2015 MSHP* "Full Utilization" (100 percent) is defined as an average of 936 dialysis treatments per station per year.

FMC Brandon's application shows that the total number of dialysis treatments from September 2015 through August 2016 is 17,166 and the number of operational, existing ESRD hemo-dialysis stations is twenty-three (23).

Based on the *FY 2015 MSHP*, the applicant calculated the existing ESRD facility's Utilization Rate as:

936 treatments x 23 stations = 21,528 treatments per year

17,166 (Applicant's treatments per year)
21,528 (Applicant's Existing ESRD Facility Treatments)

= 79.73% Utilization Rate

Based on the utilization data submitted by FMC Brandon, FMC Brandon has a utilization rate of 79.73 for the 12 months prior to the month of CON application submission.

SHP Criterion 3- Need for the Establishment of ESRD Satellite Facilities

The proposed application is not for the establishment of a new ESRD facility; therefore, Criterion 3 is not applicable.

SHP Criterion 4 - Number of Stations

The applicant currently operates twenty-three (23) hemo-dialysis ESRD stations and based on CON # R-0898 approved September 24, 2015, the applicant was approved for the addition of seven (7) ESRD stations and is currently proposing to add an additional six (6) ESRD stations. Therefore, the proposed project is not a new ESRD facility.

SHP Criterion 5 - Minimum Utilization

The applicant states that ESRD Policy Statement #10 regarding Minimum Utilization does not apply to the proposed project. The applicant further states that FMC Brandon is not proposing the establishment of a new facility but only to expand their existing facility.

SHP Criterion 6 - Minimum Services

FMC Brandon affirmed that the facility will provide, at a minimum, social, dietetic, and rehabilitative services.

SHP Criterion 7 - Access to Needed Services

FMC Brandon affirmed that the applicant will provide reasonable access to equipment/facilities for such needs as vascular access and transfusions required by stable maintenance ESRD patients.

SHP Criterion 8 - Hours of Operation

FMC Brandon will operate six days per week between the hours of 6:00 a.m. to 4:30 p.m. The applicant affirmed that alternate arrangements will be made for those patients needing after-hours treatments.

SHP Criterion 9 - Home Training Program

FMC Brandon affirmed that a home-training program will be made available and it will counsel all patients on the availability of and eligibility requirements to enter the home/self-dialysis program.

SHP Criterion 10 - Indigent/Charity Care

The applicant affirmed that they will provide a reasonable amount of indigent/charity care and serve approximately 2% indigent/charity care patients. The applicant states it will serve all ESRD patients, including Medicaid and Medicare recipients.

SHP Criterion 11 - Facility Staffing

The applicant included a proposed list of staff by category, position qualification guidelines (minimum education and experience requirements), and specific duties. The applicant indicates that the proposed project will not require any additional full-time equivalent employees.

SHP Criterion 12 - Staffing Qualifications

The applicant asserts that the staff of the facility will meet, at a minimum, all requirements and qualifications as stated in 42 CFR, Subpart D, Section 494.140 as listed under SHP Criterion 12.

SHP Criterion 13 - Staffing Time

The applicant affirmed that when the unit is in operation, at least one (1) R.N. will be on duty and at least two (2) persons will be present for each dialysis shift, one of which will be an R.N. In addition, the applicant affirms that the medical director or a designated physician will be on site or on call at all times when the unit is in operation. When the ESRD facility is not in operation, the applicant states that the medical director or a designated physician and one R.N. will be on call.

SHP Criterion 14 - Data Collection

The applicant affirmed that it shall record and maintain all required data listed under SHP Criterion 14 and shall make it available to the Mississippi State Department of Health as required by the Department.

SHP Criterion 15 - Staff Training

The applicant affirmed that it will provide an ongoing training program for nurses and technicians in dialysis techniques at the facility.

SHP Criterion 16 -Scope of Privileges

The applicant affirmed that it will provide access to doctors of medicine or osteopathic medicine licensed by the State of Mississippi who possess qualifications established by the proposed governing body of the facility.

SHP Criterion 17 - Affiliation with a Renal Transplant Center

The applicant affirmed that they have an affiliation agreement with the University of Alabama at Birmingham Renal Transplant Center and three other entities. The applicant provided an existing copy of the Renal Transplant Agreement between FMC Brandon and with the University of Alabama at Birmingham Renal Transplant Center. The application also contained an Affiliation Agreement between Central Mississippi Medical Center and Bio Medical Applications of MS.

B. General Review (GR) Criteria

Chapter 8 of the *Mississippi Certificate of Need Review Manual, Revised September 1, 2011*, addresses general criteria by which all CON applications are reviewed. This application is in substantial compliance with general review criteria contained in the manual.

GR Criterion 1- Consistency with the *State Health Plan*

The application was reviewed for compliance with the *FY 2015 Mississippi State Health Plan* as discussed above.

GR Criterion 2 – Long Range Plan

The applicant states that its long range plan is to continue to provide high quality, easy to access ESRD services for patients in need of dialysis services in the Rankin County area as well as nearby outlying areas. The applicant suggests that the proposed expansion will make it easier for patients to find better slot times for dialysis treatment as well as accommodation for future patient growth.

GR Criterion 3 – Availability of Alternatives

The applicant asserts that the only feasible alternative was to not file the proposed application for the addition of hemo-dialysis stations; however, the applicant suggests that the alternative option doesn't promote progressive healthcare. The applicant states that the expansion of stations will improve the availability of

treatment, making dialysis services more convenient. The applicant therefore decided that expanding FMC Brandon ESRD hemo-dialysis stations was the best option to continue providing dialysis services in the most effective and efficient manner.

GR Criterion 4 - Economic Viability

The applicant provided a three-year projected operating statement and it indicates that the total operating revenue over a projected three year period shows an increase from \$5,868,251 to \$9,068,530. A financial feasibility study is not required for the proposed project. In addition, the statement reflects net incomes for the first three years of operation for the project (see Attachment 1).

The applicant asserts that the proposed project will expand FMC Brandon by adding six (6) ESRD hemo-dialysis stations and the project will not increase the cost of dialysis services for patients or Medicaid. In addition, the applicant's affiliation with the Fresenius network and its integrated delivery system helps to control the cost of healthcare associated with the proposed project.

GR Criterion 5 - Need for the Project

According to FMC Brandon, dialysis services will continue to be provided to underserved patients, including low income persons, racial and ethnic minorities, women, handicapped persons and other underserved groups, and the elderly.

FMC Brandon states that its utilization is expected to stay substantially the same with a possible slight increase due to the additional stations. The applicant affirms that dialysis is not an elective service but is required for patients diagnosed with ESRD. The applicant insists that the proposed project seeks to increase the availability of care to its patients, not to increase utilization. The applicant suggests that the six (6) ESRD stations addition should result in the availability of more desirable treatment slot times, which may slightly increase the facility's utilization as patients see more convenient treatment times.

The application contains 20 letters of support regarding the proposed project. The Department did not receive any letters of opposition concerning the proposed project.

GR Criterion 6 - Access to the Facility or Service

FMC Brandon states that all patients of the service area, including Medicaid recipients, charity/medically indigent patients, racial and ethnic minorities, women, handicapped persons and the elderly have access and will continue have access to the services of the of its ESRD dialysis services. The proposed project will ensure that Medicare, Medicaid and medically indigent patients residing in and around Rankin County will have quality access to care. FMC Brandon asserts that the

facility's normal business hours will be from 6:00 a.m. to 4:30 p.m., six days per week; however, alternate times are available by arrangement.

The applicant submits the following percentage of gross patient revenue (GPR) and actual dollar amount of health care provided to medically indigent care patients for the projected amounts for the two years following completion of the proposed project:

**Medically Indigent Care Patients
 Gross Patient Revenue**

	Medically Indigent *	GPR Dollar Amount
Historical Year 2014	N/A	N/A
Historical Year 2015	2%	\$2,927.30
Projected Year 1	2%	\$4,012.44
Projected Year 2	2%	\$5,299.66

*Note: Patients without a payor source receive benefits after a 90-day waiting period. The 90 day waiting period results in what is considered medically indigent/charity care at FMC Brandon.

GR Criterion 7 - Information Requirement

The applicant affirms that it will record and maintain the information required by this criterion and make it available to the Mississippi State Department of Health within 15 business days of request.

GR Criterion 8 - Relationship to Existing Health Care System

The *FY 2015 MSHP* shows that there are two ESRD facilities located in Rankin County: FMC-Brandon located at 141 Gateway Drive, Brandon, Mississippi & NRI Brandon located at 101 Christian Drive, Brandon, Mississippi. Staff determined that NRI Brandon is located approximately two (2) miles from FMC Brandon. The applicant submits that the target population served by FMC Brandon should remain substantially the same.

The applicant states that while patients will continue to receive life-saving dialysis treatments at the facility, they will continue to deal with the effects of overcrowding on treatment times. The applicant believes that if the proposed expansion is not allowed, daily time slots will be limited, leaving less options for patients to receive treatment and will result in more missed appointments; which doesn't promote the continuity of care.

The application contained copies of the existing ESRD facility's current transfer and hospital agreements between FMC Brandon and the University of Mississippi Medical Center.

GR Criterion 9 - Availability of Resources

FMC Brandon submits that it currently has the following required personnel for the proposed project: registered nurses, nephrologists, technical/paramedical, administrative/managerial employees at its existing facility. The applicant states that in the event there is a shortage of staff, their affiliation with other ESRD facilities in the area will allow them to supplement and share personnel from other affiliated facilities when necessary. The applicant states that the proposed project will not require any additional full-time equivalent employees.

GR Criterion 10 – Relationship to Ancillary or Support Services

The applicant states that it currently has all necessary support and ancillary services for FMC Brandon and there will be no change in cost or charges as a result of the proposed project.

GR Criterion 11 - Delivery of Health Services

The applicant asserts that FMC Brandon participates in health training programs in the area to meet the clinical needs in the surrounding area.

GR Criterion 12 – Access by Health Professional Schools

As mentioned in GR Criterion 11, the applicant asserts that FMC Brandon participates in health training programs in the area to provide clinical experience for students in the surrounding area.

GR Criterion 14 - Construction Projects

The applicant confirms that the proposed project does not involve any new construction or renovations.

GR Criterion 16 - Quality of Care

The applicant asserts that the proposed project will improve accessibility and enhance the quality of care currently given at the existing facility.

IV. FINANCIAL FEASIBILITY

A. Capital Expenditure Summary

The total estimated capital expenditure is allocated as follows:

	Item	Cost (\$)	Percent (%) of Total
a.	Construction Cost – New	0	0%
b.	Renovation Cost	0	0%
c.	Capital Improvements	0	0
d.	Total Fixed Equipment Cost	6,600	33.50%
e.	Total Non-Fixed Equipment Cost	0	0%
f.	Land Cost	0	0%
g.	Site Preparation Cost	0	0%
h.	Fees (Architectural, Consultant, etc.)	0	0%
i.	Contingency Reserve	0	0%
j.	Capitalized Interest	0	0%
k.	Other Cost	13,100	66.50%
	Total Proposed Capital Expenditure	\$19,700	100.00%

B. Method of Financing

The applicant indicates that cash reserves will be used to fund the proposed capital expenditure.

C. Effect on Operating Cost

The applicant’s three-year projected operating statement is presented in Attachment 1.

D. Cost to Medicaid/Medicare

The applicant projects the cost to third party payors as follows:

Payor Mix	Utilization Percentage (%)*	First Year Revenue (\$)
Medicare	64.54%	3,787,116
Medicaid	1.59%	93,521
Commercial	30.40%	1,784,065
Self Pay	0.05%	2,927
Charity Care	0.07%	4,012
Other	3.35%	196,610
Total	100%	\$5,868,251

* Applicant’s percentages were off due to rounding. Staff determined percentages above.

V. RECOMMENDATIONS OF OTHER AFFECTED AGENCIES

The Division of Medicaid was provided a copy of this application and the Department received written comments from the agency. For the expansion of an existing ESRD facility, the Division of Medicaid does not foresee any increase in allowable costs to Medicaid as a result of the project and does not oppose the transaction.

VI. CONCLUSION AND RECOMMENDATION

This project is in substantial compliance with the overall objectives, criteria and standards of the *2015 Mississippi State Health Plan*, with regard to the expansion of ESRD facilities; Chapter 8 of the *Mississippi Certificate of Need Review Manual, 2011 Revision*; and all adopted rules, procedures, and plans of the Mississippi State Department of Health.

Therefore, the Division of Health Planning and Resource Development recommends approval of the application submitted by Bio-Medical Applications of Mississippi, Inc. d/b/a Fresenius Medical Care Dialysis Services of Rankin County - Brandon for the Expansion of ESRD Stations.

Attachment 1

Bio-Medical Applications of Mississippi, Inc., d/b/a Fresenius Medical Care Dialysis Services of Rankin County - Brandon Three-Year Operating Statement (with Project)			
	Year 1	Year 2	Year 3
Revenue			
Inpatient	\$ 0	\$ 0	\$ 0
Outpatient	5,868,251	7,744,365	9,068,530
Gross Patient Revenue	\$ 5,868,251	\$ 7,744,365	\$ 9,068,530
Charity Care	0	0	0
Deductions from Revenue	0	0	0
Net Patient Revenue	\$ 5,868,251	\$ 7,744,365	\$ 9,068,530
Other Operating Revenue	0	0	0
Total Operating Revenue	\$ 5,868,251	\$7,744,365	\$ 9,068,530
Operating Expenses			
Salaries	\$1,0635,437	\$1,412,959	\$1,662,750
Benefits	374,922	497,214	585,114
Supplies	1,246,107	1,636,355	1,906,785
Services	0	0	0
Lease	463,306	463,306	463,306
Depreciation	348,813	348,813	348,813
Interest	0	0	0
Other	941,571	1,236,446	1,440,791
Total Expenses	\$4,440,155	\$5,595,092	\$6,407,558
Net Income (Loss)	\$1,428,096	\$2,149,273	\$2,660,972
Assumptions			
Inpatient days*	0	0	0
Outpatient days*	0	0	0
Procedures	17,783	23,118	26,676
Charge per outpatient day	N/A	N/A	N/A
Charge per inpatient day	N/A	N/A	N/A
Charge per procedure	\$ 330	\$ 335	\$ 340
Cost per inpatient day	N/A	N/A	N/A
Cost per outpatient day	N/A	N/A	N/A
Cost per procedure	\$ 250	\$ 242	\$ 240